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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/509,874

09/28/2005

Harry C Dorn

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06/05/2009

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EXAMINER

PERREIRA, MELISSA JEAN

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/509,874	Applicant(s) DORN ET AL.	
	Examiner MELISSA PERREIRA	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/1/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

1. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

2. The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 60/368960, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The provisional 60/368960 provides for C₈₀ but does not provide C_m where m = 60-200 and therefore claim 10 is not granted benefit of the priority date of 4/2/02 but is granted a priority date of 4/2/03 of PCT/US03/10137 which provides for the limitations of m = 60-200.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1,2,6-9,20-23 are rejected under 35 U.S.C. 102(e) as being anticipated by Miller et al. (US 6,471,942).

5. The applied reference has a common inventor with the instant application.

Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

6. Miller et al. (US 6,471,942) teaches a trimetallic nitride template endohedral metallofullerene compound having at least one diagnostic atom (first atom) and at least one treatment atom (second atom) encapsulated within a fullerene cage such that the diagnostic atom is different from the treatment atom (column 2, especially lines 1-7 and 17-23). The fullerene cage may be C₆₈, C₇₈ or C₈₀; the diagnostic atom (first atom) may be gadolinium, erbium, europium, etc.; the treatment atom (second atom) may be holmium, actinium, yttrium, etc. (column 2, especially lines 51+; column 3, lines 1-13). The first and second atoms are different and therefore inherently have different imaging contrast properties.

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7. Miller et al. further teaches of the method of administering the trimetallic nitride template endohedral metallofullerene into a body for the method of imaging (i.e. magnetic resonance imaging) and treating an area of the body (column 2, especially lines 8-11 and 14-31; column lines 36-48).

8. Claims 1,2,6-9,11,12 and 16-19 are rejected under 35 U.S.C. 102(a & e) as being anticipated by Dorn et al. (US 6,303,760B1).

9. The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

10. Dorn et al. (US 6,303,760B1) teaches of trimetallic nitride endohedral metallofullerene compounds, $A_{3-n}X_nN@C_m$ ($n = 0-3$) where the first metal may be a rare earth element and a group IIIB element (i.e. A is Yb, Tm, Er, Ho, Y, Gd, La) and the second metal may be a rare earth element and a group IIIB element (i.e. X = Y, La, Gd, Ho, Sc, Er, Tm, Yb) (column 1, lines 50-61; column 2, lines 49-60). The first and second atoms are different and therefore inherently have different imaging contrast properties. Two separate trimetallic nitride endohedral metallofullerene compounds disclosed may include $Sc_3N@C_{80}$, $Er_3N@C_{80}$ (column 3, lines 30-33) where each has a single and different metal atom. Endohedral refers to encapsulation of atoms inside the fullerene cage network (column 4, lines 32-40). The intended use, contrast agent, is not

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generally afforded any patentable weight and since the combination leads to the same compounds as claimed, they would be expected to be capable of performing the same intended use. "The recitation of a new intended use for an old product does not make a claim to that old product patentable." *In re Schreiber*, 44 USPQ2d 1429 (Fed. Cir. 1997).

11. Claim 10 is rejected under 35 U.S.C. 102(a) as being anticipated by Iezzi et al. (*Nano. Lett.* **2002**, 2, 1187-1190).

12. Iezzi et al. (*Nano. Lett.* **2002**, 2, 1187-1190) teaches of $\text{Lu}_3\text{N}@\text{C}_{80}$ (p1187, fig 1).

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 1-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dorn et al. (US 6,303,760B1) in view of Bolskar et al. (US 7,208,132B2) and in further view of Bartl et al. (*SPIE* **1996**, 2854, 17-27).

15. Dorn et al. (US 6,303,760B1) discloses trimetallic nitride endohedral metallofullerene compounds, $\text{A}_{3-n}\text{X}_n\text{N}@\text{C}_m$ ($n = 0-3$) where the first metal may be a rare earth element and a group IIIB element (i.e. A is Yb, Tm, Er, Ho, Y, Gd, La) and the second metal may be a rare earth element and a group IIIB element (i.e. X = Y, La, Gd, Ho, Sc, Er, Tm, Yb) (column 1, lines 50-61; column 2, lines 49-60). The first and

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second atoms are different and therefore have different imaging contrast properties.

Two separate trimetallic nitride endohedral metallofullerene compounds disclosed may include $\text{Sc}_3\text{N}@C_{80}$, $\text{Er}_3\text{N}@C_{80}$ (column 3, lines 30-33) where each trimetallic nitride endohedral metallofullerene has a single and different metal atom. Endohedral refers to encapsulation of atoms inside the fullerene cage network (column 4, lines 32-40). Dorn et al. does not explicitly disclose that the first metal may be a Lu atom.

16. Bolskar et al. (US 7,208,132B2) discloses metal-containing endohedral fullerenes (contrast-enhancing agent) for use in clinical MRI, nuclear medicine, etc. (column 18, lines 46+; column 19, lines 1-50). The metal-containing endohedral fullerenes have the structure $M_m@C_{2n}$ where M is a lanthanide metal, transition metal, etc.; $m = 1, 2, 3$, or higher and n is an integer (column 10, lines 44+). Bolskar et al. teaches that the lanthanide metals (rare earth), M, may include Lu, Y, Gd, Tb, Ho, Dy, etc. (column 14, lines 1-19).

17. Bartl et al. (*SPIE* **1996**, 2854, 17-27) discloses endohedral metallofullerenes $\text{Lu}@C_{78}$ and $\text{Lu}@C_{80}$ for the examination of ESR (electron spin resonance) spectroscopy (p18, table 1). For the most metallofullerenes both single filled and double filled fullerenes were measured but the mass spectrometric signals of single filled fullerenes are much larger than the signals of double and higher filled metallofullerenes, not excluding trimetallic Lu metallofullerenes (p17, abstract).

18. At the time of the invention it would have been obvious and predictable to one skilled in the art to substitute the rare earth metal, Lu, of Bolskar et al. for the first metal of Dorn et al., which comprises rare earth elements and a group IIIB element, as both

Bolskar et al. and Dorn et al. al. teach of endohedral metallofullerenes. There are a finite number of rare earth metals and thus the substitution of one rare earth metal for another is predictable.

19. Dorn et al. teaches of endohedral metallofullerenes where the first metal comprises a rare earth metal encapsulated within a C₈₀ cage. At the time of the invention it would have been obvious to one skilled in the art to substitute the rare earth metal, Lu, of Bartl et al. for the first metal of Dorn et al., which comprises a rare earth element and a group IIIB element, as Bartl et al. teaches that Lu may be encapsulated within C₈₀ cage and that double and higher filled metallofullerenes containing Lu are possible but were not reported because they have smaller mass spectrometric signals.

20. Also, it is obvious to those skilled in the art to make known substitutions on compounds that are similar in structure and function to observe the effects on the function of such compounds and to use the observations/data to further manipulate a compound to generate the desired effect.

Double Patenting

21. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

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F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

22. Claims 20, 22 and 23 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 and 6 of U.S. Patent No. US 6,471,942B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the trimetallic nitride endohedral metallofullerene compounds having a first and second atom of the instant application encompass the trimetallic nitride template endohedral metallofullerenes having a diagnostic atom and a treatment atom of US 6,471,942B1. The method of contrast imaging of the instant application encompasses the method for imaging and treating an area of the body of US 6,471,942B1 as both methods involve administering the trimetallic nitride endohedral metallofullerene compounds and imaging/tracing an area of the body. The trimetallic nitride endohedral metallofullerene compounds of the instant application have a second atom (i.e. holmium, yttrium) which encompasses the treatment atom (second atom) of US 6,471,942B1 (i.e. holmium, actinium, yttrium, etc.) and therefore the trimetallic nitride endohedral metallofullerene compounds of the instant application will automatically allow for the treatment atom to react.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA PERREIRA whose telephone number is (571)272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/Melissa Perreira/
Examiner, Art Unit 1618